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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/777,018 | 02/05/2001 | Roger N. Hastings | 5236-000215 | 5479 |

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| EXAMINER |
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BUNIN, ANDREW M

| ART UNIT | PAPER NUMBER |
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3743

DATE MAILED: 05/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | | |
|------------------------------|------------------------|--|---------------------|--|
| Office Action Summary | Application No. | | Applicant(s) | |
| | 09/777,018 | | HASTINGS ET AL. | |
| | Examiner | | Art Unit | |
| | Andrew M. Bunin | | 3743 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 January 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 34-42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 34-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 February 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this

Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 34-37 and 39 are rejected under 35 U.S.C. 102(b) as being anticipated by Ueda et al. (US 5681260). Ueda et al. disclose a device comprising a catheter 8 having a proximal and a distal end and a lumen therebetween (Figure 28). A catheter is defined as “a hollow flexible tube for insertion into a body cavity, duct, or vessel to allow the passage of fluids or distend a passageway.” (dictionary.com). Therefore, the catheter 8 of Ueda et al. reads on this definition. Ueda et al. continues to disclose a support structure 22/94/140 in the lumen adjacent the distal end. Ueda et al. also discloses one or more optical conduits 16/25 in the catheter 8, each having a distal end supported by the support structure 22/94/140 and one or more magnetic members (19/82/20/95) disposed in the distal end of the catheter 8. In addition, the distal end of the catheter 8 is oriented by one or more magnetic members (19/82/20/95) that align relative to the direction of an externally applied magnetic field from magnetic generator 11/31 (Abstract). Lastly, Ueda et al. teach one or more optical conduit 16/25 in the distal end is inherently capable of being rotated within a support structure 22/94/140. The support structure as stated can be

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broadly interpreted as section 140 or 22 within a tubular device. It is considered inherent that the optical conduits can be rotated within the catheter device manually since the conduits are loosely inserted within the support structure allowing the conduit to be rotatable. In addition, articulation frames 22 that can be broadly interpreted as a support structure are connected rotatably with each other; therefore, the optical conduits 16/25 that fit adjacent to these support structures would inherently be capable of rotation as well (column 8, lines 31-41).

As for claim 35, the magnet members (19/82/20/95) disposed in the distal end of the catheter that orient the distal end to align relative to an applied magnetic field 11/31, whereby the distal end is oriented by changing the direction of the externally applied magnetic field to cause the magnet members to align relative to the magnetic field (Abstract).

In regards to claims 36 and 37, Ueda et al. teach a support structure 140 comprising one or more magnetic members 142 (Figure 25). Ueda et al. continue to disclose a support structure comprising a sheath 84/85 (Figure 11).

As for claim 39, Ueda et al. disclose one or more magnetic members 142 disposed in the distal end of the catheter 8, whereby the distal end is oriented by the one or more magnetic members that align relative to the direction of an externally applied magnetic field 11/31. In addition, the one or more magnet members 142 are positioned within the catheter 8 and are inherently capable of being rotatable within the catheter since the magnet is manually inserted into channel 140, therefore, the magnet is capable of being manually rotated in any direction.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 38 and 40-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ueda et al. in view of Conlan et al. (US 5904147) and further in view of Goldenberg (US 4830460). Ueda et al. disclose a vivisecting forceps (column 12, line 17) or the like except doesn't explicitly teach a device comprising a laser ablation tool. However, Conlan et al. disclose a catheter device including an optical conduit 42 and being magnetically oriented by an external magnetic field as shown in Figure 7. Conlan et al. teach the tip of the catheter as having an ablation instrument (column 10, lines 25-31). Goldenberg further teaches a guidance system with an ultraviolet laser ablation tool at the catheter distal end (column 3, lines 20-21). Therefore, it would have been obvious to a person having ordinary skill in the art at the time of the invention to modify Ueda et al. by replacing the forceps with a laser ablation tool of Conlan et al. and Goldenberg in order to remove specific blockage in a user's body.

As for claim 42, Ueda et al. teach a support structure 94/140 comprising a passage for a guide wire. Goldenberg discloses a similar support structure in a sleeve 72 that explicitly teaches a passage for a guidewire 70 (column 13, lines 65-68). Therefore, it would have been obvious for a person having ordinary skill

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in the art at the time of the invention to advance a guidewire through this passage to ensure an optical fiber remains in alignment.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 34-37 and 39 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-26 of U.S. Patent No. US 5681260 in view of Ueda et al. The sheath in claims 7, 18, and 19 reads on a support structure of claim 1 of the instant application. An energy source in claims 1, 18, and 19 can be broadly interpreted as an optical conduit or vice versa. Lastly, the magnetically active element in claims 1 and 18-20 reads on the magnetic members in claim 1 of the instant application. As for

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the optical conduit or energy source as being rotatable, Ueda et al. teach one or more optical conduit 16/25 in the distal end as being inherently capable of rotation within a support structure 22/94/140. The support structure as stated can be broadly interpreted as section 140 or 22 within a tubular device. It is considered inherent that the optical conduits can be rotated within the catheter device manually since the conduits are loosely inserted within the support structure allowing the conduit to be rotatable. In addition, articulation frames 22 that can be broadly interpreted as a support structure are connected rotatably with each other; therefore, the optical conduits 16/25 that fit adjacent to these support structures would inherently be capable of rotation as well (column 8, lines 31-41). Therefore, it would have been obvious to a person having ordinary skill in the art at the time of the invention to modify the device of the claims of '026 with the optical conduit being rotatable in order to position an optical conduit at a desired position before or during insertion.

Claims 38 and 40-42 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-26 of U.S. Patent No. US 5681260 and Ueda et al. in view of Conlan et al., and further in view of Goldenberg. Ueda et al. disclose a vivisecting forceps (column 12, line 17) or the like except doesn't explicitly teach a device comprising a laser ablation tool. However, Conlan et al. disclose a catheter device including a optical conduit 42 and being magnetically oriented by an external magnetic field as shown in Figure 7. Conlan et al. teach the tip of the catheter as having an ablation instrument (column 10, lines 25-31). Goldenberg further teaches a

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guidance system with an ultraviolet laser ablation tool at the catheter distal end (column 3, lines 20-21). Therefore, it would have been obvious to a person having ordinary skill in the art at the time of the invention of the claims of '026 and Ueda et al. by replacing the forceps with a laser ablation tool of Conlan et al. and Goldenberg in order to remove specific blockage in a user's body.

Response to Arguments

Applicant's arguments with respect to claims 34-42 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: US 5916210, US 5353807, US 5125888, US 5706827, and US 4244362

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew M. Bunin whose telephone number is (571)272-4801. The examiner can normally be reached on Monday - Friday, 8 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on (571)272-4791. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

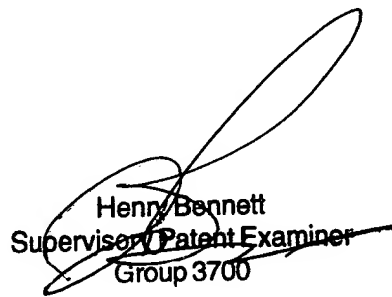
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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



AMB

4/27/06



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